IDW 1617

207.1300US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mark CHASIN et al.
Serial No.:	10/057,301
Filed:	January 25, 2002
For:	**Local Anesthetic and Method of Use**
Examiner:	Travers, Russell S. Art Unit: 1617

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Alexandria, VA 22313-1450

May 20, 2004

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (17 Sheets) for consideration by the Examiner in connection with the examination of the above-identified patent application.

In accordance with 37 C.F.R. § 1.98(a), copies of U.S. patent documents, foreign patent documents and publications are enclosed.

Applicants also respectfully advise the Examiner of the following commonly assigned U.S. Patents and applications:

U.S. Patent No. 5,747,060, "Prolonged Local Anesthesia with a Colchicine Agent," issued May 5, 1998;

U.S. Patent No. 5,942,241, "Formulations and Methods for Providing Prolonged Local Anesthesia," issued August 24, 1999;

U.S. Patent No. 6,248,345, "Prolonged Anesthesia in Joints and Body Spaces," issued June 19, 2001;

FORM PTO-1083

Docket No.: 207.1300US
Date: May 20, 2004

ASSISTANT COMMISSIONER FOR PATENTS
Alexandria, VA 22313-1450

In re application of: Mark CHASIN, et al.
Serial No.: 10/057,301
Filed: January 25, 2002
For: **Local Anesthetic and Method of Use**

S i r:

Transmitted herewith is an **Information Disclosure Statement** in the above-identified application.

[ ] Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.
[ ] A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
[ ] No fee for additional claims is required.
[ ] A filing fee for additional claims calculated as shown below, is required:

[X] Also transmitted herewith are:
[ ] Petition for extension under 37 C.F.R. 1.136 (in duplicate)
[X] Other: **-Form PTO-1449 (17 pages) and copies of references cited therein**
- Exhibit A- which contains pending claims of Appl. Serial No. 10/345,567, which contains the same specification as US Patent No. 10/345,567, listed on the enclosed Form PTO-1449 as document NC.

[X] Check(s) in the amount of **$180. 00** is/are attached to cover:
[ ] Filing fee for additional claims under 37 C.F.R. 1.16
[ ] Petition fee for extension under 37 C.F.R. 1.136
[X] Other: **Information Disclosure Statement**

[X] The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
[X] Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
[X] Any patent application processing fees under 37 C.F.R. 1.17.
[X] Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

Leslye B. Davidson, Reg. No. 38,854
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U.S. Patent No. 6,451,335, "Formulations and Methods for Providing Prolonged Local Anesthesia," issued September 17, 2002;

U.S. Patent No. 6,514,516, "Formulations and Methods for Providing Prolonged Local Analgesia," issued February 4, 2003;

U.S. Patent No. 6,521,259, "Formulations and Methods for Providing Prolonged Local Anesthesia," issued February 18, 2003;

U.S. Patent No. 6,524,607, " Formulations and Methods for Providing Prolonged Local Anesthesia," issued February 25, 2003

U.S. Patent No. 6,699,908, "Methods for Providing Safe Local Analgesia," issued March 2, 2004; and

U.S. Patent Application Serial No. 10/345,567, "Formulations and Methods for Providing Prolonged Local Anesthesia," filed January 16, 2003.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii), the Examiner's attention is directed to Exhibit A, attached herewith, which contains the following:

(i) the pending claims for U.S. Patent Application Serial No. 10/345,567, which has the same specifications as U.S. Patent No. 6,524,607, listed on the enclosed Form PTO-1449 as document NC.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy be promptly forwarded.

The present Information Disclosure Statement is filed under 37 C.F.R. § 1.97(c), after the mailing of a first Office Action on the merits. Accordingly, a check in the amount of **$180.00** is enclosed. If it is determined that any additional fee is due, the Commissioner is hereby authorized to charge such fee to Attorney Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
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Our Ref. 207.1300 May 20, 2004 LBD/RVZ/oi
Re: Application of: Mark CHASIN, et al.
Serial No. 10/057,301
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Enclosed:
- Form PTO- 1083 (1 page);
- Information Disclosure Statement (3 pages);
- Form PTO-1449 (17 pages) and copies of references cited therein

Exhibit A -which contains pending claims of Appl. Serial No. 10/345,567

- Check in the amount of $ 180.00

Hand Delivered to Examiner Travers
RECEIVED BY:

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Exhibit A -which contains pending claims of Appl. Serial No. 10/345,567

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Exhibit A

Pending Claims-U.S. Application Serial No. 10/345,567, filed January 16, 2003. DDK docket No. 2071015BN2CON

21. A formulation for inducing sustained regional local anesthesia or analgesia in a patient comprising:

a plurality of substrates in a pharmaceutically acceptable medium, said substrates comprising a local anesthetic and an effective amount of a biocompatible, biodegradable controlled release material comprising a polymer selected from the group consisting of polyanhydrides, copolymers of lactic acid and glycolic acid, poly(lactic) acid, poly(glycolic) acid, polyesters, polyorthoesters, proteins, polysaccharides and combinations thereof to provide a controlled release of said local anesthetic when said formulation is implanted or injected in a patient, said biocompatible, biodegradable controlled release material being capable of degrading at least fifty percent in less than two years following implantation or injection into the patient and prolonging the release of said local anesthetic from said substrates in-vitro, when measured using the United States Pharmacopeia/National Formulary Paddle Method II, said substrates being included in said formulation in an amount sufficient to obtain reversible local numbness and/or analgesia when said formulation is implanted or injected in a patient, and

a sodium channel modulator

22. The formulation of claim 21, wherein the sodium channel modulator is (i) incorporated into and/or onto said substrates; or (ii) incorporated into said pharmaceutically acceptable medium, or (iii) incorporated into said substrates and also incorporated into said pharmaceutically acceptable medium.

23. The formulation of claim 21, wherein said modulator is selected from the group consisting of aminopyridine, benzamil, diazoxide, 5,5-diphenylhydantoin, minoxidil, tetraethylammonium, valproic acid, nifedipine, nitrendipine, verapamil, and mixtures thereof.

24. The formulation of claim 21, wherein said substrates are microspheres.

25. The formulation of claim 21, wherein said substrates are microcapsules.

26. The formulation of claim 21, wherein the modulator is incorporated in the pharmaceutically acceptable medium in a concentration of from about 0.01% to about 5%, by weight.

27. The formulation of claim 21, wherein the modulator is incorporated in the pharmaceutically acceptable medium in a concentration of from about 0.05% to about 1.5%, by weight.

28. The formulation of claim 21, wherein the local anesthetic is incorporated into said controlled release material at a percent loading of 0.1% to 90%, by weight.

29. The formulation of claim 21, wherein the local anesthetic is selected from the group consisting of bupivacaine, ropivacaine, dibucaine, etidocaine, tetracaine, lidocaine, xylocaine, procaine, chloroprocaine, prilocaine, mepivacaine, mixtures thereof, and salts thereof.

30. The formulation of claim 21, wherein the substrates are in a form selected from the group consisting of slabs, rods, beads, pellets, microparticles, microspheres, microcapsules, spheroids and pastes.

31. The formulation of claim 21, wherein the substrates include from about 65% to about 80% local anesthetic, by weight.

32. The formulation of claim 21, wherein said formulation is injected.

33. The formulation of claim 21, wherein said formulation is implanted.

34. The formulation of claim 21, wherein the local anesthetic is bupivacaine.

35. A formulation for inducing sustained regional local anesthesia or analgesia in a patient comprising:

a plurality of substrates in a pharmaceutically acceptable medium, said substrates comprising a local anesthetic and an effective amount of a biocompatible, biodegradable, controlled release material comprising a polymer selected from the group consisting of polyanhydrides, copolymers of lactic acid and glycolic acid, poly(lactic) acid, poly(glycolic) acid, polyesters, polyorthoesters, proteins, polysaccharides and combinations thereof to provide a controlled release of said local anesthetic when said formulation is implanted or injected in a patient, capable of degrading at least fifty percent in less than two years following implantation or injection into the patient, and prolonging the release of said local anesthetic from said substrates in-vitro, said substrates being included in said formulation in an amount sufficient to obtain reversible local numbness and/or analgesia when said formulation is implanted or injected in a patient; and

a sodium channel modulator, said modulator being (i) incorporated into and/or onto said substrates; or (ii) incorporated into said pharmaceutically acceptable medium, or (iii) incorporated into said substrates and also incorporated into said pharmaceutically acceptable medium, said formulation providing an *in vitro* release of said local anesthetic using the United States Pharmacopeia/National Formulary Paddle Method II of from about 10 to about 60 percent after 24 hours, from about 20 to about 80 percent release after 48 hours and from about 40 to about 100 percent release after 72 hours, said formulation providing a reversible local anesthesia at the site when administered *in vivo* of at least about 24 hours.

36. The formulation of claim 35, wherein said modulator is selected from the group

consisting of aminopyridine, benzamil, diazoxide, 5,5-diphenylhydantoin, minoxidil, tetraethylammonium, valproic acid, nifedipine, nitrendipine, verapamil, and mixtures thereof.

37. The formulation of claim 35, wherein said substrates are microspheres.

38. The formulation of claim 35, wherein said substrates are microcapsules.

39. The formulation of claim 35, wherein the modulator is incorporated in the pharmaceutically acceptable medium in a concentration of from about 0.01% to about 5%, by weight.

40. The formulation of claim 35, wherein the modulator is incorporated in the pharmaceutically acceptable medium in a concentration of from about 0.05% to about 1.5%, by weight.

41. The formulation of claim 35, wherein the local anesthetic is selected from the group consisting of bupivacaine, ropivacaine, dibucaine, etidocaine, tetracaine, lidocaine, xylocaine, procaine, chloroprocaine, prilocaine, mepivacaine, mixtures thereof, and salts thereof.

42. The formulation of claim 35, wherein the local anesthetic is bupivacaine.

43. The formulation of claim 35, wherein the substrates include from about 65% to about 80% local anesthetic, by weight.

44. The formulation of claim 35, wherein said formulation is injected.

45. The formulation of claim 35, wherein said formulation is implanted.

46. A formulation for inducing sustained regional local anesthesia or analgesia in a patient comprising a plurality of substrates comprising a local anesthetic, a sodium channel modulator, and an effective amount of a biocompatible, biodegradable controlled release material comprising a polymer selected from the group consisting of polyanhydrides, copolymers of lactic acid and glycolic acid, poly(lactic) acid, poly(glycolic) acid, polyesters, polyorthoesters, proteins, polysaccharides and combinations thereof to provide a controlled release of said local anesthetic when said formulation is implanted or injected in a patient, said biocompatible, biodegradable controlled release material being capable of degrading at least fifty percent in less than two years following implantation or injection into the patient and prolonging the release of said local anesthetic from said substrates in vitro, when measured using the United States Pharmacopeia/National Formulary Paddle Method II, said substrates being included in said formulation in an amount sufficient to obtain reversible local numbness and/or analgesia when said formulation is implanted or injected in a patient.

47. The formulation of claim 46, wherein said modulator is selected from the group consisting of aminopyridine, benzamil, diazoxide, 5,5-diphenylhydantoin, minoxidil,

tetraethylammonium, valproic acid, nifedipine, nitrendipine, verapamil, and mixtures thereof.

48. The formulation of claim 46, wherein said substrates are microspheres.

49. The formulation of claim 46, wherein said substrates are microcapsules.

50. The formulation of claim 46, wherein at least a portion of said modulator is incorporated in said substrates.

51. The formulation of claim 46, wherein the modulator is incorporated in the substrate in a concentration of from about 0.01% to about 5%, by weight.

52. The formulation of claim 46, wherein the local anesthetic is selected from the group consisting of bupivacaine, ropivacaine, dibucaine, etidocaine, tetracaine, lidocaine, xylocaine, procaine, chloroprocaine, prilocaine, mepivacaine, mixtures thereof, and salts thereof.

53. The formulation of claim 46, wherein the substrates include from about 65% to about 80% local anesthetic, by weight.

54. The formulation of claim 46, wherein the substrates are microspheres.

55. The formulation of claim 46, wherein the substrates are microcapsules.

56. The formulation of claim 46, wherein said formulation is injected.

57. The formulation of claim 46, wherein said formulation is implanted.

58. The formulation of claim 21, wherein the modulator is incorporated in the substrates in a concentration of from about 0.01% to about 5%, by weight.

59. The formulation of claim 35, wherein the modulator is incorporated in the substrates in a concentration of from about 0.01% to about 5%, by weight.

60. The formulation of claim 46, wherein the modulator is incorporated in the substrates in a concentration of from about 0.01% to about 5%, by weight.

61. The formulation of claim 58, wherein a further amount of said modulator is on said substrates.

62. The formulation of claim 59, wherein a further amount of said modulator is on said substrates.

63. The formulation of claim 58, wherein the substrates are in a pharmaceutically acceptable medium and wherein a further amount of the modulator is incorporated in the pharmaceutically acceptable medium.

64. The formulation of claim 21, wherein the modulator is incorporated onto said substrates.

65. The formulation of claim 35, wherein the modulator is incorporated into said substrates and also incorporated into said pharmaceutically acceptable medium.

66. The formulation of claim 21, wherein the modulator is provided in an amount effective to prolong the duration of the local anesthetic effect for a time period greater than that possible by the use of the local anesthetic in controlled release form by itself.

FORM PTO-1449 (REV. 7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 207.1300US	SERIAL NO. 10/057,301
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT: Mark CHASIN, et al.	
	FILING DATE: January 25, 2002	GROUP : 1617

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	AA	3	9	4	3	0	6	3	3/9/76	Morishita, et al.	252	316	
	AB	4	0	8	9	8	0	0	5/16/78	Temple	252	316	
	AC	4	2	9	3	5	3	9	10/6/81	Ludwig, et al.	424	19	
	AD	4	3	8	4	9	7	5	5/24/83	Fong	427	213.36	
	AE	4	3	8	9	3	3	0	6/21/83	Tice, et al.	427	213.36	
	AF	4	6	2	2	2	1	9	11/11/86	Haynes	424	38	
	AG	4	6	5	2	4	4	1	3/24/87	Okada, et al.	424	19	
	AH	4	7	2	5	4	4	2	2/16/88	Haynes	424	490	
	AI	4	7	5	7	1	2	8	7/12/88	Domb, et al.	528	271	
	AJ	5	4	0	7	6	0	9	4/18/95	Tice, et al.	264	46	
	AK	5	6	1	8	5	6	3	4/8/97	Berde, et al.	424	501	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
													YES	NO
	AL	0	2	4	4	1	1	8	11/4/87	EPO A1	A61K	9/10		
	AM	9	2	0	7	5	5	5	5/14/92	PCT A1	A61K	9/22		
	AN	9	1	1	7	7	7	2	11/28/91	PCT	A61K	47/30		
	AO	0	1	9	5	9	0	6	02/06/86	EPA	A61K	31/71		
	AP	9	2	1	5	2	8	6	9/17/92	WO	A61K	9/22		

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AQ	Berde, C.B., et al., "Sustained Release of Dibucaine from a Biodegradable Polymer Matrix: A Potential Method for Prolonged Neural Blockade", Abstracts of Scientific Papers, 1990 Annual Meeting, Amer. Soc. Anesthesiologists, 73:A776 (Sept. 1990)
	AR	Edelman, Elazer R., et al., "Optimization of release from magnetically controlled polymeric drug release devices", Biomaterials, 14(8):621-626 (1993)
	AS	Masters, et al., Abstract No. 94.3, "Prolonged Sciatic Nerve Blockade Using Sustained Release of Veratridine From a Biodegradable Polymer Matrix", Soc. Neurosci. Abstr., 18:200 (1992)
	AT	Fong, Jones W., et al., "Evaluation of biodegradable microspheres prepared by a solvent evaporation process using sodium oleate as emulsifier", Journal of Controlled Release, 3:119-130 (1986)

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	BA	5	2	2	7	1	6	5	07/13/93	Domb, et al.	424	450	
	BB	3	1	8	5	6	2	5	05/25/65	Brown	167	82	
	BC	3	7	5	5	5	5	8	08/28/73	Scribner	424	47	
	BD	3	9	7	2	9	9	5	08/03/76	Tsuk, et al.	424	28	
	BE	4	0	3	4	7	5	8	07/12/77	Theeuwes	128	260	
	BF	4	0	9	3	7	0	9	06/06/78	Choi, et al.	424	19	
	BG	4	1	3	1	6	4	8	12/26/78	Choi, et al.	424	22	
	BH	4	1	3	8	3	4	4	02/06/79	Choi, et al.	252	1	
	BI	4	2	2	6	8	4	8	10/07/80	Nagai, et al.	424	19	
	BJ	4	2	5	0	1	6	3	02/10/81	Nagai, et al.	424	14	
	BK	4	3	6	9	1	7	2	01/18/83	Schor, et al.	424	19	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
													YES	NO
	BL	2	9	3	0	2	4	8	02/12/81	Germany	B01J	13/02	x	
	BM	1	1	4	3	2	8	9	3/22/83	Canada	A61K	9/50		
	BN	0	4	3	0	4	7	4	6/5/91	EP (A1)	A61K	9/70		
	BO	WO	93	2	0	1	3	8	10/14/93	PCT (A2)	C08L			
	BP	WO	94	0	5	2	6	5	3/17/94	PCT (A1)	A61K	9/20		

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	BQ	Fong JW "Microencapsulation by Solvent Evaporation and Organic Phase Separation Processes," pp. 81-108, chapter 5 from Controlled Release Systems: Fabrication Technology, Ed. Dean Hsieh, Ph.D., Vol. 1
	BR	Masters, David B., et al. ,"Prolonged Regional Nerve Blockade by Controlled Release of Local Anesthesia from a Biodegradable Polymer Matrix", Anesthesiology, 79:340-346 (1993)
	BS	Miyazaki, S., et al., "External control of drug release: controlled release of insulin from a hydrophilic polymer implant by ultrasound irradiation in diabetic rats", J. Pharm. Pharmacol., 40:716-717 (1988)
	BT	Sato, T., et al., "Porous Biodegradable Microspheres for Controlled Drug Delivery. I. Assessment of Processing Conditions and Solvent Removal Techniques", Pharmaceutical Research, 5:21-30 (1988)

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	CA	4	4	3	4	1	5	3	02/28/84	Urquhart,et al.	424	22	
	CB	4	5	3	0	8	4	0	07/23/85	Tice, et al.	514	179	
	CC	4	5	4	2	0	2	5	09/17/85	Tice, et al.	424	78	
	CD	4	6	2	2	2	4	4	11/11/86	Lapka, et al.	427	213.32	
	CE	4	6	5	0	6	6	5	03/17/87	Kronenthal, et al.	424	435	
	CF	4	4	0	4	1	8	3	09/13/83	Kawata, et al.	424	19	
	CG	4	7	1	3	2	4	4	12/15/87	Bawa, et al.	424	429	
	CH	4	7	3	5	9	4	5	04/05/88	Sakamoto, et al.	514	279	
	CI	5	0	7	5	1	0	9	12/24/91	Tice, et al.	424	88	
	CJ	3	3	3	7	4	0	0	08/22/67	Smith	167	52	
	CK	3	5	0	7	9	5	2	04/21/70	Rednick, et al.	424	22	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
													YES	NO
	CL	WO	96	4	1	6	1	6	12/27/96	PCT (A1)	A61K	9/14		
	CM	2	0	3	4	1	8	2	6/4/80	UK (A)	A61K	9/00		
	CN	WO	92	1	5	2	8	6	9/17/92	PCT (A1)	A61K	9/22		
	CO	0	7	9	7	9	8	8	10/01/97	EPA A2	A61K	9/16		
	CP	2	5	9	2	7	9	1	07/17/87	FR				X

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	CQ	Schneider, Markus, M.D., et al., "A Preferential Inhibition of Impulses in C-fibers of the Rabbit Vagus Nerve by Veratridine, an Activator of Sodium Channels", Anesthesiology, 74:270-280 (1991)
	CR	Tice, Thomas R., et al., "Preparation of Injectable Controlled-Release Microcapsules by a Solvent-Evaporation Process", Journal of Controlled Release, 2:343-352 (1985)
	CS	Wakiyama, Naoki, et al., "Preparation and Evaluation in Vitro and in Vivo of Polylactic Acid Microspheres containing Dibucaine", Chem. Pharm. Bull, 30:3719-3727 (1982)

EXAMINER	DATE CONSIDERED

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FORM PTO-1449 (REV. 7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

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U.S. PATENT DOCUMENTS

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	DA	3 5 3 5 4 1 9	10/20/70	Siegrist, et al.	424	22	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
							YES	NO
	DB	9 5 1 3 7 9 9	05/26/95	PCT (A1)	A61K	9/50		

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	DC	Duncan, et al., "Treatment of Upper Extremity Reflex Sympathetic Dystrophy with Joint Stiffness Using Sympatholytic Bier Blocks and Manipulation" Orthopedics 11(6), pp. 883-886, (1988)
	DD	Flanagan, et al., "Intra-articular injection for pain relief in patients awaiting hip replacement", Ann. Royal Coll. Surg. Eng., Vol. 70, pp 156-157 (1988)
	DE	Glasser, et al., "The perioperative use of corticosteroids and bupivacaine in the management of lumbar disc disease", J. Neurosurg., Vol. 78, pp. 383-387, (1993)
	DF	Guttu, et al., "Delayed Healing of Muscle After Injection of Bupivacaine and Steroid", Annals of Dentistry, 49:5-8, (1990)
	DG	Hall, et al., "Acute effects of intravenous glucocorticoid on cat spinal motor neuron electrical properties", Brain Research, Vol. 240, pp. 186-190, (1982)
	DH	Sandrock and Warfield, "Epidural Steroids and Facet Injections", Ch. 29 Principles and Practice of Pain Management, Warfield, C.A., editor (McGraw-Hill, Inc. 1993)
	DI	Waldman, et al., "The Relief of Body Wall Pain Secondary to Malignant Hepatic Metastases by Intercostal Nerve Block with Bupivacaine and Methylprednisolone", J. Pain Symptom Management, 3(1), 39-43 (1988), (see in particular page 42, column 2)
	DJ	Bonica, John J. and F. Peter Buckley, "Regional Analgesia folkmanwith Local Anesthetics", The Management of Pain II; pp. 1883-1966, (1990), Lea & Febiger (Eds.) Second Edition
	DK	Lewis, D.H., et al., "The Use of In Vitro Release Methods to Guide the Development of Controlled-Release Formulations", 9th International Symposium on Controlled Release of Bioactive Maerials, Sponsored by Controlled Release Society, Inc., pp. 61-64.
	DL	Masters, D.B., et al., "Meeting for the American Society of Anesthesiologists, Vol. 75:A680, (1991)
	DM	Devor, et al., 1983, "Axoplasmic Transport Block Reduces Ectopic Impulse Generation in Injured Peripheral Nerves", pp. 73-85
	DN	Schnebel, et al., "The Use of Oral Colchicine for Low-Back Pain", 1987, pp. 354-357
	DO	March, et al., "Biodegradable Microspheres Containing a Colchicine Analogue Inhibit DNA Synthesis in Vascular Smooth Muscle Cells", 1994, pp. 1929-1933
	DP	CA 125:104914, , Joanne Curley, et al., "Prolonged regional nerve blockade: Injectable biodegradable bupivacaine/polyester microspheres"
	DQ	L.S. Goodman, et al., "The Pharmacological Basis of Therapeutics", Fourth Edition, 1970, The MacMillan Co., page 372

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	FILING DATE: January 25, 2002	GROUP : 1617

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	EA	3,736,466	06/05/73	Schmitt, et al.	29	458	
	EB	3,773,919	11/20/73	Boswell, et al.	424	19	

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							YES	NO
	EC	WO 99/01141	01/14/99	PCT (A1)	A61K	9/50		

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	ED	Vol. IA "Drug Information for the Health Care Professional", USP DI, 1989, Ninth Edition, Anesthetics (Mucosal-Local), pp. 183-84; 196-97; 201-03.
	EE	Setterstrom, Tice, Lewis and Meyers, "Controlled Release of Antibiotics from Biodegradable Microcapsules fro Wound Infection Control", U.S. Army Institute of Dental Research, (1982), 12 pages.
	EF	Abstract: Archer DR, et al. "Changes in slow axonal transport of tubulin induced by local application of colchicine to rabbit vagus nerve", Acta Physiol Scand 1994 Jan. 150(1):57-65
	EG	Abstract: Le Corre, et al., "Spinal controlled delivery of bupivacaine from DL-lactic acid oligomer microspheres", J. Pharm Sci 1995 Jan. 84(1) 75-78
	EH	Abstract: Gradus-Pizlo, et al., "Local delivery of biodegradable microparticles containing colchicine or a.....", J.Am.Coll. Cardiol. 1995 Nov. 26(6) 1549-57
	EI	Abstract: Penickova V., et al., "Vinblastin iontophoresis in treating intractable pain", Acta Univ Palacki Olomuc Fac Med 1990 128:37-47 .
	EJ	Abstract: Kantner, et al., "Regulatory mechanisms for substance P in the dorsal horn during a nociceptive stimulus: axoplasmic transport vs. electrical activity., Brain Res., Oct. 22, 1986 385(2):282-90.
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	EN	Baguley, Bruce C., et al., "Inhibition of Growth of Colon 38 Adenocarcinoma by Vinblastine and Colchicine: Evidence for a Vascular Mechanism", Eur.J. Cancer, Vol. 27, No. 4, pages 482-487 (1991)
	EO	Jean-Marc Malinovsky, et al., "Motor and Blood pressure effects of epidural sustained-release bupivacaine from polymer microspheres: A dose-response study in rabbits," Anesth. Analg. 1995, 81:519-524.

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	FA	3	8	4	4	2	8	5	10/29/74	Laby	128	260	
	FB	3	9	7	2	9	9	9	08/03/76	Tsuk	424	78	
	FC	3	9	7	6	0	7	1	08/24/76	Sadek	128	260	
	FD	3	9	9	1	7	6	6	11/16/76	Schmitt et al.	128	335.5	
	FE	4	0	1	1	3	1	2	03/08/77	Reuter, et al.	424	78	
	FF	4	0	7	6	7	9	8	02/28/78	Casey, et al.	424	22	
	FG	4	1	1	8	4	7	0	10/03/78	Casey, et al.	424	19	
	FH	4	1	4	4	3	1	7	03/13/79	Higuchi, et al.	424	21	
	FI	4	1	6	6	1	0	7	08/28/79	Miller, et al.	424	19	
	FJ	4	1	6	6	8	0	0	09/04/79	Fong	252	316	
	FK	4	4	7	9	9	1	1	10/30/84	Fong	264	4.6	
	FL	4	5	8	5	6	5	1	04/29/86	Beck, et al.	424	88	
	FM	4	7	5	6	9	0	7	07/12/88	Beck, et al.	424	85	
	FN	4	7	5	7	1	2	8	07/12/88	Domb, et al.	528	271	
	FO	4	8	9	1	2	2	5	01/02/90	Langer, et al.	424	428	

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													YES	NO
	FP	WO	98	5	1	2	9	0	11/19/98	PCT (A2)	A61K	31/00		

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	FQ	XP-002144657 Li, J. and Yan, S., "Analgesic dilator for use in cervical and uterine operations", (Abstract of CN1091041).
	FR	Lim, J.-O., et al., "Prolonged Sciatic nerve blockade II: Local Anesthetic-Polymer Microsphere", Abstract Supplement, Abstracts of Scientific Papers 1995 Annual Meeting of American Society of Anesthesiologists, J. Amer. Soc. Anesth. Vol. 83, No. 3A, A810 (1995).
	FS	Jain, et al., "Controlled release of drugs from injectable in situ formed biodegradable PLGA microspheres: effect of various formulation variables," Eur. J. Pharm. Biopharm., Vol. 50(2): 257-262 (2000).
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	FU	

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	GA	4 8 0 1 7 3 9	01/31/89	Franz, et al.	560	185	
	GB	5 0 0 7 7 9 0	04/16/91	Shell	424	451	
	GC	5 1 0 0 6 6 9	03/31/92	Hyon, et al.	424	426	
	GD	5 1 4 3 6 6 1	09/01/92	Lawter, et al.	264	4.3	
	GE	5 2 6 4 2 0 7	11/23/93	Bommelaer, et al	424	69	
	GF	5 2 7 2 1 3 9	12/21/93	Cary, Jr.	514	171	
	GG	5 3 3 0 4 5 2	07/19/94	Zook	604	307	
	GH	5 4 9 2 9 0 1	02/20/96	Fabunan	514	171	
	GI	5 5 4 0 9 1 2	07/30/96	Roorda, et al.	424	422	
	GJ	5 5 4 3 1 5 6	08/06/96	Roorda, et al.	424	484	
	GK	5 6 5 0 1 7 3	07/22/97	Ramstack, et al.	424	489	
	GL	4 5 5 7 9 2 5	12/10/85	Lindahl, et al.	424	19	
	GM	5 6 5 4 0 0 8	08/05/97	Herbert, et al.	424	489	
	GN	5 7 4 7 0 6 0	05/05/98	Sackler, et al.	424	426	

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	HA	2 1 7 4 7 9 6	10/3/39	Luzzi	32	34	2/5/37
	HB	2 8 3 5 6 2 8	5/20/58	Saffir	167	84	4/1/57
	HC	3 8 8 7 6 9 9	6/3/75	Yolles	424	19	12/29/70
	HD	4 0 0 1 3 8 8	1/4/77	Shell	424	14	7/2/75
	HE	4 0 3 9 6 5 3	8/2/77	DeFoney, et al.	424	19	7/21/75
	HF	4 0 7 0 3 4 7	1/24/78	Schmitt	260	77.5 D	8/16/76
	HG	4 1 6 4 5 6 0	8/14/79	Folkman, et al.	424	22	1/5/77
	HH	4 1 7 5 3 2 6	11/27/79	Goodson	433	80	10/26/77
	HI	4 2 7 6 8 8 0	7/7/81	Malmin	128	221	12/14/79
	HJ	4 3 2 1 0 3 8	3/23/82	Porteous	433	136	7/18/80
	HK	4 4 1 9 3 4 0	12/6/83	Yolles	424	19	11/20/80

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							YES	NO
	HL							
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	HR	
	HS	
	HT	

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	IA	4 5 6 8 5 3 5	2/4/86	Loesche	424	19	7/16/84
	IB	4 5 6 8 5 3 6	2/4/86	Kronenthal, et al.	424	22	2/8/85
	IC	4 5 6 9 8 3 7	2/11/86	Suzuki, et al.	424	28	6/1/84
	ID	4 5 8 5 6 5 1	4/29/86	Beck, et al.	424	88	12/18/80
	IE	4 5 9 7 9 6 0	6/1/86	Cohen	424	28	6/3/83
	IF	4 6 2 3 5 8 8	11/18/86	Nuwayser, et al.	428	402.24	11/18/86
	IG	4 6 8 5 8 8 3	8/11/87	Jernberg	433	136	7/26/85
	IH	4 7 1 6 2 0 3	12/29/87	Casey, et al.	525	408	9/5/86
	II	4 7 5 6 9 0 7	7/12/88	Beck, et al.	424	85	1/24/86
	IJ	4 7 6 7 6 2 8	8/30/88	Hutchinson	424	426	6/29/87
	IK	4 7 8 0 3 2 0	10/25/88	Baker	424	493	4/29/86

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							YES	NO
	IL							
	IM							
	IN							
	IO							
	IP							

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	IR	Beck, Lee R., et al., "Poly(DL-Lactide-co-glycolide)/Norethisterone Microcapsules: an Injectable Biodegradable Contraceptive", Biology of Reproduction, Vol. 28, pages 186-195 (1983)
	IS	Bissery, M.C., et al., "A Study of Process Parameters in the Making of Microspheres by the Solvent Evaporation Procedure", EXPO-Congr. Int. Technol. Pharm., 3rd, pages 233-239 (1983)
	IT	Bodmeier, R., et al., "Solvent selection in the preparation of poly(DL-lactide) microspheres prepared by the solvent evaporation method", International Journal of Pharmaceutics, Vol. 43, pages 179-186, (1988)

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	JA	4	7	8	9	7	2	6	12/6/88	Hutchinson	528	354	4/2/87
	JB	4	8	6	1	6	2	7	8/29/89	Mathiowitz, et al.	427	213.31	5/1/87
	JC	4	8	7	4	6	1	2	10/17/89	Deasy	424	425	2/3/88
	JD	4	8	8	2	1	6	8	11/21/89	Casey, et al.	424	468	9/5/86
	JE	4	8	8	3	6	6	6	11/28/89	Sabel, et al.	424	422	4/29/87
	JF	4	8	8	8	1	7	6	12/19/89	Langer, et al.	424	426	6/12/87
	JG	4	8	9	1	2	2	5	1/2/90	Langer, et al.	424	428	1/21/86
	JH	4	8	9	2	7	3	6	1/9/90	Goodson	424	435	6/3/88
	JI	4	9	0	6	4	7	4	3/6/90	Langer, et al.	424	428	5/21/84
	JJ	4	9	1	9	9	3	9	4/24/90	Baker	424	493	7/8/88
	JK	4	9	3	3	1	8	2	6/12/90	Higashi, et al.	424	425	9/29/89

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													YES	NO
	JL													
	JM													
	JN													
	JO													
	JP													

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	JR	Bodmeier, R., et al., "Polylactic acid microspheres containing quinidine base and quinidine sulphate prepared by the solvent evaporation technique. II. Some process parameters influencing the preparation and properties of microspheres", J. Microencapsulation, Vol. 4, No. 4, pages 289-297 (1987)
	JS	Hill, S.A., et al., "Vinca Alkaloids: Anti-vascular Effects in a Murine Tumour", Euro. J. Cancer, Vol. 29A, No. 9, pages 1320-1324 (1993)
	JT	Jalil, R., et al., "Microencapsulation using poly(L-lactic acid) I: Microcapsule properties affected by the preparative technique", J. Microencapsul., Vol. 6, No. 4, pages 473-484 (Oct-Dec) (1989)

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	KA	5	0	0	0	8	8	6	3/19/91	Lawter, et al.	264	4.3	5/26/87
	KB	5	0	0	4	6	0	2	4/2/91	Hutchinson	424	78	5/12/86
	KC	5	0	1	3	5	5	3	5/7/91	Southard, et al.	424	426	8/29/89
	KD	5	0	1	9	3	7	9	5/28/91	Domb, et al.	424	78	7/31/87
	KE	5	0	1	9	4	0	0	5/28/91	Gombotz, et al.	424	497	5/1/89
	KF	5	0	3	2	3	8	4	7/16/91	Yeh, et al.	424	49	1/27/89
	KG	5	0	8	4	2	6	7	1/28/92	Damani	424	426	11/17/89
	KH	5	1	1	4	7	1	8	5/19/92	Damani	424	422	9/20/90
	KI	5	1	2	2	3	6	7	6/17/92	Ron, et al.	424	80	3/31/89
	KJ	5	1	8	8	8	3	7	2/23/93	Domb	424	450	10/3/91

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	KL													
	KM													
	KN													

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	KO	Lin, Shan-Yang, et al., " Insulin Controlled-release Microcapsules to Prolong the Hypoglycemic Effect in Diabetic Rats", Biomat. Art. Cells, Art. Org., Vol. 16, No. 4, pages 815-828 (1988)
	KP	Lin, Shan-Yang, et al., "Microencapsulation and controlled release of insulin from polylactic acid microcapsules", Biomat. Med. Dev., Art. Org., Vol. 13, Nos. 3&4, pages 187-201 (1985-86)
	KQ	Mathiowitz, E., et al., "Polyanhydride Microspheres as Drug Carriers. II. Microencapsulation by Solvent Removal", Journal of Applied Polymer Science, Vol. 35, pages 755-774 (1988)

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	LA	5	1	9	8	2	2	0	3/30/93	Damani	424	426	8/24/90
	LB	5	2	2	2	5	2	9	6/29/93	Zoltan	141	4	10/30/92
	LC	5	2	2	5	4	4	1	7/6/93	Vogel, et al.	514	557	6/18/87
	LD	5	2	3	6	3	5	5	8/17/93	Brizzolara, et al.	433	80	10/5/90
	LE	5	2	5	2	7	0	1	10/12/93	Jarrett, et al.	528	354	7/6/90
	LF	5	4	0	1	5	0	7	3/28/95	Lewis	424	426	11/9/92
	LG	5	7	0	0	4	8	5	12/23/97	Berde, et al.	424	501	05/01/95
	LH	5	9	4	2	2	4	1	08/24/99	Chasin, et al.	424	426	
	LI	5	9	2	2	3	4	0	07/13/99	Berde, et al.	424	426	09/16/96
	LJ	6	0	4	6	1	8	7	04/04/00	Berde, et al.	514	180	09/16/96
	LK	6	0	0	8	3	1	8	12/28/99	Zhao, et al.	528	398	06/17/98

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	LL													
	LM													
	LN													
	LO													
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	LR	Splenlehauer, G., et al., "*In vitro* and *in vivo* degradation of poly(D,L lactide/glycolide) type microspheres made by solvent evaporation method", Biomaterials, Vol. 10, pages 557-563 (October 1989)
	LS	Thies, Curt, "Microcapsules as Drug Devices Systems", Crit. Rev. Biomed. Eng., Vol. 8, Issue 4, pages 335-383 (1982)
	LT	Windholz M., et al. The Merck Index, 10th Edition, page 37, Abstract # 225 (1983)

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	MA	6	1	5	3	2	1	2	11/28/00	Mao, et al.	424	426	10/02/98
	MB	5	9	5	2	4	5	1	09/14/99	Zhao	528	272	06/23/98
	MC	6	0	5	1	5	7	6	04/18/00	Ashton, et al.	514	255.06	01/29/97
	MD	6	1	0	3	2	5	5	08/15/00	Levene, et al.4	424	426	04/16/99
	ME	5	1	7	6	9	0	7	01/05/93	Leong	424	78.08	08/13/91
	MF	5	1	9	4	5	8	1	03/16/93	Leong	528	398	03/09/89

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	MH	Thomas R. Tice, et al. Biodegradation of Microcapsules and Biomedical Devices Prepared with Resorbable Polyesters, Southern Research Institute, University of Alabama. (pages 21-23)
	MI	William T. Buchanan, et al. Systemic Effects of epinephrine-impregnated retraction cord in fixed partial denture prosthodontics, JADA, Vol. 104, April 1982.
	MJ	David B. Masters, et al., Sustained Local Anesthetic Release from Bioerodible Polymer Matrices: A Potential Method for Prolonged Regional Anesthesia, Pharmaceutical Research, Vol. 10, No. 10, pp. 1527-32,1993.
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	MN	Richard L. Dunn, et al., Monolithic Fibers for Controlled Delivery of Tetracycline, Southern Research Institute (pp. 157-159)
	MO	Thomas R. Tice, Controlled Release of Ampicillin and Gentamicin from Biodegradable Microcapsules, Southern Research Institute.
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	MQ	Marshall Devor, et al., Corticosteroids Suppress Ectopic Neural Discharge Originating in Experimental Neuromas, Pain, 22 pp. 127-137, (1985).
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FORM PTO-1449 (REV. 7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 207.1300US	SERIAL NO. 10/057,301
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT: Mark CHASIN, et al.	
	FILING DATE: January 25, 2002	GROUP : 1617

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	NA	6 5 1 4 5 1 6	02/04/03	Chasin, et al.	424	426	06/29/99
	NB	6 5 2 1 2 5 9	02/18/03	Chasin, et al.	424	489	03/10/00
	NC	6 5 2 4 6 0 7	02/25/03	Goldenheim, et al.	424	426	03/10/00
	ND	6 4 5 1 3 3 5	09/17/02	Goldenheim, et al.	424	426	07/02/98
	NE	6 4 2 6 3 3 9	07/30/02	Berde, et al.	514	180	04/03/00
	NF	6 2 3 8 7 0 2	05/29/01	Berde, et al.	424	489	07/12/99
	NG	6 2 1 4 3 8 7	04/10/01	Berde, et al.	424	501	09/17/97
	NH	5 0 6 1 4 9 2	10/29/91	Okada, et al.	424	423	
	NI	6 2 4 8 3 4 5	06/19/01	Goldenheim, et al.	424	426	
	NJ	5 2 4 4 6 7 8	09/14/93	Legros, et al.	424	450	
	NK						

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	NQ	Schneider, Markus, M.D., et al., "A Preferential Inhibition of Impulses in C-fibers of the Rabbit Vagus Nerve by Veratridine, an Activator of Sodium Channels", Anesthesiology, 74:270-280 (1991)
	NR	Tice, Thomas R., et al., "Preparation of Injectable Controlled-Release Microcapsules by a Solvent-Evaporation Process", Journal of Controlled Release, 2:343-352 (1985)
	NS	Nakano et al., "Biodegradable microspheres for prolonged anesthesia", Microspheres and Drug Therapy: Pharmaceutical, Immunological and Medical Aspects, pp. 327-335 (1984).
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	NW	

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PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	OA	4 3 3 1 7 2 8	05/25/82	Theeuwes, et al.	428	215	
	OB	5 2 9 2 5 1 2	03/08/94	Schaefer, et al.	424	401	
	OC	6 2 1 7 9 1 1	04/17/01	Vaugn, et al.	424	501	07/05/96
	OD	6 1 9 7 3 2 6	03/06/01	Suzuki, et al.	424	426	10/14/98
	OE	6 1 6 2 4 6 2	12/19/00	Bolotin, et al.	424	450	
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	OH							
	OI							
	OJ							
	OK							
	OL							

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	OM	Estebe, et al., "Prolongation of spinal anesthesia with bupivacaine-loaded (DL-Lactide) microspheres", Anesth. Analg. Vol. 81(1) July 1995, pp. 99-103
	ON	Le Corre, et al., "In vitro controlled release kinetics of local anesthetics from poly (D,L-lacitde) and poly(lactide-co-glycolide) microspheres", J. Microencapsulation, vol. 14, no. 2, pp. 243-55 (1997).
	OO	Abstract: Bernardo, M.V., et al., "In vitro-controlled release of bupivacaine from albumin microspheres and a co-matrix formed by microspheres in a poly(lactide-co-glycolide) film", J. Microencapsulation, Nov.-Dec. 2000, vol. 17, pp. 721-731.
	OP	Holte, Kathrin, et al., Dexamthasone prolongs analgesia of subcutaneous bupivacaine microspheres in human volunteers, 8th European Congress on Pain Research, Rome, Sept. 20-23, 2000.
	OQ	Castillo, et al., "Glucocorticoids prolong rat sciatic nerve blockade in vivo from bupivacaine microspheres," Anesthesiology, 85:1157-66 (1996).
	OR	
	OS	

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U.S. PATENT DOCUMENTS

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	PA						
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	PL	WO 97 4 9 3 9 1	12/31/97	PCT (A1)	A61K	31/24		

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	PM	Apruzzese, William A., et al., "Bupivacaine Release from Biopolymeric Depots for the Alleviation of Postoperative Pain," Biomaterials Engineering and Devices: Human Applications, Vol. 1, pp. 295-306, (2000)
	PN	Abstract: Werner, et al., "Local Analgesia with Bupivacaine/Dexamethasone Microspheres- Dose Response after Subcutaneous Infiltration in Healthy Volunteers," Abstracts of Scientific Papers, 2001 Annual Meeting, Amer. Soc. Anesthesiologists, 95: A935 (Oct. 2001)
	PO	Abstract: Kopacz, et al., "Local Analgesic Dose-Response with Bupivacaine/Dexamethasone Polymer Microcapsules – Intercostal Nerve Blockade," Abstracts of Scientific Papers, 2001 Annual Meeting, Amer. Soc. Anesthesiologists, 95: A966 (Oct. 2001)
	PP	Maniar, et al., "In-Vitro and In-vivo Evaluation of a Sustained Release Local Anesthetic Formulation," Pharm Res., 8:10 (1991)
	PQ	Abstract of JP 8143449
	PR	
	PS	

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	QA	6	5	3	4	0	8	1	03/18/03	Goldenheim, et al.	424	426	
	QB	6	6	9	9	9	0	8	03/02/04	Sackler, et al.	514	563	
	QC	6	2	4	8	3	4	5	06/19/01	Goldenheim, et al.	424	426	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	QH													
	QI													
	QJ													
	QK													
	QL													

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	QM	Abstract: Evora, et al., "In Vivo-in Vitro Study of Biodegradable Methadone Delivery Systems," Biomaterials, 22:6, pp. 563-570 (March 2001)
	QN	Abstract: Yen, et al., "Controlled Release of Nalbuphine Propionate from Biodegradable Microspheres: in Vitro and in Vivo Studies," Int J Pharm, 220:1-2, pp. 91-9 (Jun 2001)
	QO	Press Release: "Guilford Pharmaceuticals Announces New Development Programme for Biopolymer Formulation of Lidocaine," USA, 03-21-2000.
	QP	
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	QU	
	QV	

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